



PCT

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Translation

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2141/Dr.Got/	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/EP2003/011545	International filing date (day/month/year) 18 October 2003 (18.10.2003)	Priority date (day/month/year) 20 December 2002 (20.12.2002)	
International Patent Classification (IPC) or national classification and IPC A61K 9/28			
Applicant RÖHM GMBH & CO. KG			

1.	This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.
3.	This report is also accompanied by ANNEXES, comprising: <ul style="list-style-type: none"> a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows: <ul style="list-style-type: none"> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4.	This report contains indications relating to the following items: <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand 29 May 2004 (29.05.2004)	Date of completion of this report 18 April 2005 (18.04.2005)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2003/011545

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☐ The international application as originally filed/furnished
- ☒ the description:
- pages _____ 1-33 _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- pages _____ 1-13 _____, as originally filed/furnished
- pages* _____, as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-11, 13	YES
	Claims	12	NO
Inventive step (IS)	Claims		YES
	Claims	1-13	NO
Industrial applicability (IA)	Claims	1-13	YES
	Claims		NO

2. Citations and explanations

Reference is made to the following documents:

- D1: US 2002/192285 A1 (MULYE NIRMAL) 19 December 2002 (2002-12-19)
- D2: US-B1-6 368 629 (WATANABE SHUNSUKE ET AL) 9 April 2002 (2002-04-09)
- D3: DE 39 21 403 A (EGYT GYOGYSZERVEGYESZETI GYAR) 8 February 1990 (1990-02-08)
- D4: US-B1-6 378 789 (SEAMAN JR CHARLES E ET AL) 30 April 2002 (2002-04-30)
- D5: EP-A-1 240 826 (WISSLER ERHARD) 18 September 2002 (2002-09-18)
- D6: GB-A-1 576 075 (UNION CARBIDE AUSTRALIA) 1 October 1980 (1980-10-01)
- D7: WO 91/19486 A (KALMO ENTERPRISES INC) 26 December 1991 (1991-12-26)
- D8: EP-A-0 523 847 (MCNEIL PPC INC) 20 January 1993 (1993-01-20)
- D9: US 2001/055619 A1 (WEISBROD WOLFGANG ET AL) 27 December 2001 (2001-12-27)

Novelty:

The present application does not meet the

requirements of PCT Article 33(1) because the subject matter of claim 12 lacks novelty (PCT Article 33(2)). The existence of a device comprising a triple-feed nozzle is disclosed on page 15 of the present description.

The subject matter of claims 1, 9 and 13 appears novel, since the overlapping of the spray jets as per claim 1 (and the resultant agent (claim 9)) is not disclosed by the known prior art.

Inventive step:

The present application does not meet the requirements of PCT Article 33(3) because the subject matter of claims 1-13 does not involve an inventive step (PCT Article 33(3)).

Documents D1, D2 and D7-D9 teach the use of several coatings (predominantly using Eudragit®) in producing drugs. The cited prior art also shows the use of polymers with anionic groups for desired pH ranges and the use of not more than 20 wt.% of a softening agent and not more than 5 wt.% of a non-ionic emulsifier.

Also, for the assessment of inventive step the information on page 33, example 6 of the current application appears to be significant. According to that information, mixing of the components within the spray gun results in unwanted coagulation. The problem therefore appears to lie in the spraying process, not in the choice of specific coating agent.

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Devices for implementing the current method are disclosed in D1 to D9 and, in the light of page 15 of the description, the use of triple-feed nozzles is also known to a person skilled in the art.